

Attorney Docket No.: 47675-238 (formerly 47675-14)
First Named Inventor: Isabel D.C. Markl
Filing Date: 27 October 2000
Final Office Action Dated: 19 April 2007
Date of Amendment: 19 October 2007
Examiner: Jeanine Anne Goldberg

IN THE CLAIMS:

Applicants, pursuant to 37 C.F.R. § 1.121, submit the following amendments to the claims:

1. (Currently amended) A diagnostic or prognostic assay for cancer, comprising:
 - (a) obtaining a tissue sample from a test tissue;
 - (b) performing a methylation assay on DNA from the tissue sample, wherein the methylation assay determines the methylation state of a CpG dinucleotide within ~~at least one DNA sequence selected from the group consisting of SEQ ID NO:36 and a contiguous CpG island sequence that comprises SEQ ID NO:36, wherein the CpG island sequence is a contiguous sequence of about 0.2 to about 1 kb in length that satisfies the criteria of having both a frequency of CpG dinucleotides corresponding to an Observed/Expected Ratio >0.6, and a GC Content >0.5, and wherein the methylation state of a CpG dinucleotide in SEQ ID NO:36 is representative of the state of the CpG dinucleotides in the CpG island;~~ and
 - (c) determining a diagnosis or prognosis based, at least in part, upon the methylation state of the CpG dinucleotide within the DNA sequence, compared to that of control DNA, wherein the determined methylation state is hypermethylation, and wherein the cancer is breast cancer.
- 2.-3. (Canceled)
4. (Previously presented) The diagnostic or prognostic assay of claim 1 wherein the methylation assay procedure is selected from the group consisting of MethyLight, MS-SNuPE, MSP, MCA, COBRA, and combinations thereof.
- 5.-6. (Canceled)
7. (Previously presented) A kit useful for the detection of a methylated CpG-containing nucleic acid comprising a carrier means containing one or more containers comprising:
 - (a) a container containing a probe or primer consisting of at least 12 contiguous nucleotides of a sequence selected from the group consisting of SEQ ID NOS:36 and 37, and the bisulfite-converted sequences thereof; and
 - (b) additional standard methylation assay reagents, wherein the kit, based at least in part on the probe or primer, is suitable to determine the methylation status of one or more CpG

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dinucleotides within the sequence selected from the group consisting of SEQ ID NOS:36 and 37.

8. (Previously presented) The kit of claim 7, wherein the additional standard methylation assay reagents are standard reagents for performing a methylation assay from the group consisting of MethyLight, MS-SNuPE, MSP, MCA, COBRA, and combinations thereof.

9. (Canceled)

10. (Previously presented) An isolated nucleic acid molecule consisting of a methylated or unmethylated polynucleotide sequence selected from the group consisting of sequences of SEQ ID NO:37 and the bisulfite-converted sequences thereof.

11. (Original) The nucleic acid of claim 10, wherein the nucleic acid is methylated.

12. (Original) The nucleic acid of claim 10, wherein the nucleic acid is unmethylated.

13. (Currently amended) A diagnostic or prognostic assay for cancer, comprising:

(a) obtaining a tissue sample from a test tissue;

(b) performing a methylation assay on DNA from the tissue sample, wherein the methylation assay determines the methylation state of a CpG dinucleotide ~~within at least one DNA sequence selected from the group consisting of SEQ ID NO:37 and a contiguous CpG island sequence that comprises SEQ ID NO:37, wherein the CpG island sequence is a contiguous sequence of about 0.2 to about 1 kb in length that satisfies the criteria of having both a frequency of CpG dinucleotides corresponding to an Observed/Expected Ratio >0.6, and a GC Content >0.5, and wherein the methylation state of a CpG dinucleotide in SEQ ID NO:36 is representative of the state of the CpG dinucleotides in the CpG island;~~ and

(c) determining a diagnosis or prognosis based, at least in part, upon the methylation state of the CpG dinucleotide within the DNA sequence, compared to that of control DNA, wherein the determined methylation state is hypermethylation, and wherein the cancer is prostate, breast or colon cancer.

14. (Canceled)

15. (Previously presented) The diagnostic or prognostic assay of claim 13, wherein the methylation assay procedure is selected from the group consisting of MethyLight, MS-SNuPE, MSP, MCA, COBRA, and combinations thereof.

16. (Previously presented) A diagnostic or prognostic assay for cancer, comprising:

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- (a) obtaining a tissue sample from a test tissue;
- (b) performing a methylation assay on DNA from the tissue sample, wherein the methylation assay determines the methylation state of a CpG dinucleotide within SEQ ID NO:36; and
- (c) determining a diagnosis or prognosis based, at least in part, upon the methylation state of the CpG dinucleotide, compared to that of control DNA, wherein hypermethylation of SEQ ID NO:36 is indicative of breast cancer.

17. (Previously presented) The diagnostic or prognostic assay of claim 16, wherein the methylation assay procedure is selected from the group consisting of MethyLight, MS-SNuPE, MSP, MCA, COBRA, and combinations thereof.

18. (Previously presented) A diagnostic or prognostic assay for cancer, comprising:
- (a) obtaining a tissue sample from a test tissue;
 - (b) performing a methylation assay on DNA from the tissue sample, wherein the methylation assay determines the methylation state of a CpG dinucleotide within SEQ ID NO:37; and
 - (c) determining a diagnosis or prognosis based, at least in part, upon the methylation state of the CpG dinucleotide within the DNA sequence, compared to that of control DNA, wherein hypermethylation of SEQ ID NO:37 is indicative of prostate, breast or colon cancer.

19. (Previously presented) The diagnostic or prognostic assay of claim 18, wherein the methylation assay procedure is selected from the group consisting of MethyLight, MS-SNuPE, MSP, MCA, COBRA, and combinations thereof.